News from Ed Markey

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February 17, 2005 **Kate Reinhalter**
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Markey Asks SEC Whether Drug Companies are Complying with Disclosure Requirements on Drug Studies

Washington, D.C. - Rep. Edward J. Markey (D-MA), senior member of the House Energy and Commerce Committee, today sent a letter to Securities and Exchange Commission (SEC) Chairman William Donaldson requesting information regarding drug company disclosure of post-marketing study agreements. At an Energy and Commerce hearing earlier today, Rep. Markey asked Health and Human Services (HHS) Secretary Leavitt why drug companies were not complying with their obligations to conduct such studies, and Secretary Leavitt indicated that he too was concerned about practices in this area.

Rep. Markey noted that, "A drug company's failure to meet a post-marketing study commitment made to the FDA could lead to an expedited withdrawal of the approved product from the market. This withdrawal also would likely result in significant financial loses for the company, and I believe that investors should know about this important information."

Rep. Markey added, "I am asking the SEC to evaluate whether current disclosures made by drug companies are adequate."

The FDA now grants accelerated approval to certain drugs, on the condition that the drug company commits to conducting an appropriate post-marketing confirmatory study. Under this process, a drug can be approved on the basis of preliminary studies, and the drug company does not have to meet the normal FDA standards of establishing the drug's safety and effectiveness, as long as the company agrees to conduct post-marketing studies.

If the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence, the Secretary may withdraw approval of a fast track product using expedited procedures. It appears that many companies are not completing these required studies. On March 15, 2004, the FDA submitted a report to Congress regarding the progress of required post-marketing studies. According to this report, only 33% of required drug studies and 62% of required biologics studies were proceeding on schedule or had been completed.

On December 20, 2004, Rep. Markey sent a letter asking the FDA why the companies had not fulfilled their obligations and what the FDA planned to do in order to enforce these agreements. As of today, the FDA had not responded.

The letter Rep. Markey sent today asks the SEC whether any companies are obligated to report the status of these trials to their investors and whether companies actually do disclose this information to their investors.

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“I am concerned that not only may some drug companies be shirking their responsibility to consumers but they may also be misleading their investors into believing that a company’s products have been fully approved by the FDA as safe and effective, when in fact the drug has been given only a conditional approval which is subject to revocation,”, Rep. Markey said. Rep. Markey.

“I want to know what, if anything, the SEC intends to do to address any deficiencies in current disclosure practices by the industry,” Rep. Markey concluded.

The FDA’s Center for Drug Evaluation and Research also maintains a database of all post-marketing commitments. This database is available at: http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm

Copies of the Markey letter to the SEC can be found at www.house.gov/markey.

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